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NOTICE OF ALLOWANCE AND FEE(S) DUE

26698

7590

04/30/2008

MYRIAD GENETICS INC.
INTELLECUTAL PROPERTY DEPARTMENT
320 WAKARA WAY
SALT LAKE CITY, UT 84108

EXAMINER

WOLLENBERGER, LOUIS V

ART UNIT PAPER NUMBER

1635

DATE MAILED: 04/30/2008

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/680,449 | 10/06/2003 | Liwen Huang | 1438.01 | 4490 |

TITLE OF INVENTION: RNA INTERFERENCE USING A UNIVERSAL TARGET

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO | \$1440 | \$0 | \$0 | \$1440 | 07/30/2008 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

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If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

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B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

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| maintenance fee notifica | ttions. | | | _ | | | correspondence address as ate "FEE ADDRESS" for |
|--|---|---|--|---|--|---|---|
| CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) 26698 7590 04/30/2008 MYRIAD GENETICS INC. INTELLECUTAL PROPERTY DEPARTMENT 320 WAKARA WAY | | | | Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. | | | |
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| | | | | Certificate of Mailing or Transmission I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. | | | |
| SALT LAKE C | ITY, UT 84108 | Γ | (Depositor's name) | | | | |
| | | | Γ | | | | (Signature) |
| | | | | | | | (Date) |
| APPLICATION NO. | FILING DATE | | FIRST NAMED INVENTO | R | ATTOR | RNEY DOCKET NO. | CONFIRMATION NO. |
| 10/680,449 | 10/06/2003 | | Liwen Huang | | | 1438.01 | 4490 |
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| nonprovisional | NO | \$1440 | \$0 | \$0 | | \$1440 | 07/30/2008 |
| EXAM | IINER | ART UNIT | CLASS-SUBCLASS | | | | |
| WOLLENBER | GER, LOUIS V | 1635 | 435-006000 | | | | |
| Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. | | | or agents OR, alterna (2) the name of a sin registered attorney or 2 registered patent at listed, no name will b | of up to 3 registered patent attorneys alternatively, f a single firm (having as a member a rney or agent) and the names of up to tent attorneys or agents. If no name is | | | |
| PLEASE NOTE: Un | less an assignee is ident th in 37 CFR 3.11. Comp | ified below, no assignee | THE PATENT (print or t data will appear on the of a substitute for filing a (B) RESIDENCE: (CIT | patent. If an assign n assignment. | | | cument has been filed for |
| Please check the appropri | riate assignee category or | categories (will not be pro- | rinted on the patent): | Individual 🗖 C | orporation | on or other private grou | p entity Government |
| 4a. The following fee(s) | are submitted: | 4 | b. Payment of Fee(s): (Pl | | ny previ | iously paid issue fee sl | nown above) |
| ☐ Issue Fee ☐ Publication Fee (No small entity discount permitted) ☐ Advance Order - # of Copies | | | ☐ A check is enclosed. ☐ Payment by credit card. Form PTO-2038 is attached. | | | | |
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| 5. Change in Entity Sta | , | , | _ | | | | |
| | ns SMALL ENTITY state | | b. Applicant is no lo | | | | assignee or other party in |
| interest as shown by the | records of the United Sta | tes Patent and Trademark | COffice. | the applicant, a reg | istereu a | thorney of agent, of the | assignee of other party in |
| Authorized Signature | | | | Date | | | |
| Typed or printed name | | | | Registration No. | | | |
| This collection of inform an application. Confiden submitting the complete this form and/or suggest Box 1450, Alexandria, V Alexandria, Virginia 223 | itiality is governed by 35 d application form to the ions for reducing this bu. Virginia 22313-1450. DC | CFR 1.311. The informatic JU.S.C. 122 and 37 CFR E USPTO. Time will vary rden, should be sent to the D NOT SEND FEES OR | on is required to obtain on 1.14. This collection is ear depending upon the induction office the complete process of the compl | retain a benefit by stimated to take 12 ividual case. Any c cer, U.S. Patent and FO THIS ADDRES | the publi minutes omments Tradem S. SEND | ic which is to file (and to complete, including s on the amount of tim ark Office, U.S. Depar O TO: Commissioner fo | by the USPTO to process) gathering, preparing, and e you require to complete tment of Commerce, P.O. or Patents, P.O. Box 1450, |

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| 10/680,449 | 10/06/2003 | Liwen Huang | 1438.01 | 4490 | | |
| 26698 75 | 26698 7590 04/30/2008 | | | EXAMINER | | |
| MYRIAD GENE | TICS INC. | WOLLENBERGER, LOUIS V | | | | |
| | PROPERTY DEPART | ART UNIT | PAPER NUMBER | | | |
| 320 WAKARA W. SALT LAKE CIT | | | 1635 DATE MAILED: 04/30/200 | 8 | | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

| | Application No. | Applicant(s) |
|---|---|--|
| | 10/680,449 | HUANG ET AL. |
| Notice of Allowability | Examiner | Art Unit |
| | Louis Wollenberger | 1635 |
| The MAILING DATE of this communication apperall claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI of the Office or upon petition by the applicant. See 37 CFR 1.313 | (OR REMAINS) CLOSED in this ap or other appropriate communication IGHTS. This application is subject t | plication. If not included n will be mailed in due course. THIS |
| 1. X This communication is responsive to the replies filed 10/15 | 5/07 and 2/8/08. | |
| 2. ☑ The allowed claim(s) is/are <u>1-34</u> . | | |
| 3. Acknowledgment is made of a claim for foreign priority una) All b) Some* c) None of the: 1. Certified copies of the priority documents have 2. Certified copies of the priority documents have 3. Copies of the certified copies of the priority documents have International Bureau (PCT Rule 17.2(a)). * Certified copies not received: Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. | been received. been received in Application No cuments have been received in this of this communication to file a reply | national stage application from the |
| 4. A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give 5. CORRECTED DRAWINGS (as "replacement sheets") must (a) including changes required by the Notice of Draftspers 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's | es reason(s) why the oath or declara et be submitted. con's Patent Drawing Review(PTO | ation is deficient. -948) attached |
| Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1. each sheet. Replacement sheet(s) should be labeled as such in the sheet. DEPOSIT OF and/or INFORMATION about the deposit attached Examiner's comment regarding REQUIREMENT. | .84(c)) should be written on the drawi he header according to 37 CFR 1.121 sit of BIOLOGICAL MATERIAL | ngs in the front (not the back) of (d). must be submitted. Note the |
| Attachment(s) 1. ☐ Notice of References Cited (PTO-892) 2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material | 5. ☐ Notice of Informal F 6. ☐ Interview Summary Paper No./Mail Da 7. ☒ Examiner's Amend 8. ☐ Examiner's Statem 9. ☐ Other /Sean R McGarry/ Primary Examiner, Art Uni | r (PTO-413), te ment/Comment ent of Reasons for Allowance |

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EXAMINER'S COMMENT

Status of Application/Amendment/Claims

Applicant's response, including the amendments to the claims, filed 2/8/2008 to the

Notice of Non-Compliant Amendment, mailed 1/8/08, is acknowledged.

With entry of the amendment filed on 2/8/2008, claims 1-34 are pending.

Applicant's response filed 15 October 2007 to the Non-Final Rejection mailed 5/15/2007

has been considered. Rejections and/or objections not reiterated from the previous office action

mailed 5/15/2007 are hereby withdrawn. The text of those sections of Title 35, U.S. Code not

included in this action can be found in a prior Office action.

It is noted for the record that for purposes of the examination of the instant claims the

Examiner has relied on the special meaning of the limitation "a chimeric RNA transcript"

provided by the specification at page 16, lines 28-30. The claims have been construed by the

Office according to this special meaning.

Claim Rejections - 35 USC § 112, second paragraph—withdrawn

The rejection of Claims 16–29 and 31–33 under 35 U.S.C. 112, second paragraph, as

being indefinite is withdrawn in view of Applicant's arguments, which are found persuasive.

Claim Rejections - 35 USC § 112, first paragraph—withdrawn

The rejection of Claims 16–29 and 31–33 under 35 U.S.C. 112, first paragraph, as failing

to comply with the written description requirement is withdrawn in view of Applicant's

arguments, which are found persuasive.

Claim Rejections - 35 USC § 101 and 112, first paragraph—withdrawn

The rejection of Claims 16–34 under 35 U.S.C. 101, and therefore 35 USC 112, because the claimed invention is not supported by either a credible, specific and substantial utility or a well established utility is withdrawn in view of Applicant's arguments, which are found persuasive.

The further rejection of Claims 18–34 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn in view of Applicant's amendments to the claims.

Claim Rejections - 35 USC § 103—withdrawn

The rejection of Claims 16–20 and 27–34 under 35 U.S.C. 103(a) as being unpatentable over Sijen et al. (2001) *Cell* 107:465–476; Pal-Bhadra et al. (1998) *Cell* 99: 35–46; Voinnet et al. (1998) *Cell* 95:177–187; Fire et al. (1990) *Gene* 93:189–198; Kennerdell et al. (1998) *Cell* 95:1017-1026; and Elbashir et al. (2001) *Nature* 411:494-498 is withdrawn in view of Applicant's amendments to the claims.

Allowable subject matter

Claims 16-34 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 1-15, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement as set forth in the Office action mailed on 5/2/2005 is hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or

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divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 1-34 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LW Examiner AU1635 April 14, 2008

/Sean R McGarry/ Primary Examiner, Art Unit 1635